PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61F 2/24	A1	(11) International Publication Number: WO 92/19184
		(43) International Publication Date: 12 November 1992 (12.11.92)

(21) International Application Number: PCT/EP92/01017

(22) International Filing Date: 8 May 1992 (08.05.92)

(30) Priority data:
91 107 446.6 8 May 1991 (08.05.91) EP
(34) Countries for which the regional or international application was filed: DE et al.

(71) Applicant (for all designated States except US): NIKA HEALTH PRODUCTS LIMITED [LI/LI]; Städtle 36, FL-9490 Vaduz (LI).

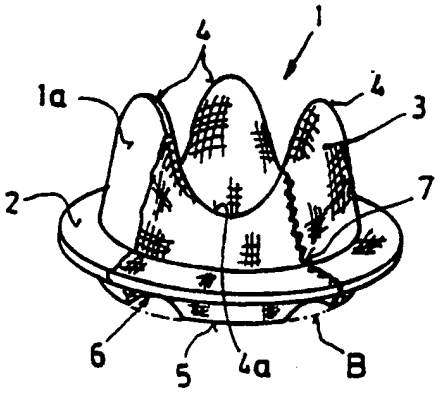
(72) Inventors; and
(75) Inventors/Applicants (for US only) : RELIGA, Zbigniew [PL/PL]; Aleja 3-Maja 2/175, Warszawa (PL). STOLARZEWICZ, Bogdan [PL/PL]; Warszawska 70, Katowice (PL). CICHON, Romuald [PL/PL]; Olimpijska 35/29, Bytom (PL). KRZYSKOW, Marek [PL/PL]; Szkolna 18/21, Swietochlowice (PL). STOZEK, Jolanta [PL/PL]; Ziolowa 46, Katowice (PL).

(74) Agent: BÜCHEL, Kurt, F.; Bergstrasse 297, FL-9495 Triesen (LI).

(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, RU, SD, SE, SE (European patent), SN (OAPI patent), TD (OAPI patent), TG (OAPI patent), US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SUPPORT FOR A HEART VALVE PROSTHESIS



(57) Abstract

A hart valve prosthesis (1) is formed from a support (1a) having a textile covering (3). The support (1a) is formed as a single piece and consists of flat, closed, preferably thermoplastic material which itself has an approximately hollow cylindrical or hollow conical shape.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FI	Finland	ML	Mali
AU	Australia	FR	France	MN	Mongolia
BB	Barbados	GA	Gabon	MR	Mauritania
BE	Belgium	GB	United Kingdom	MW	Malawi
BF	Burkina Faso	GN	Guinea	NL	Netherlands
BG	Bulgaria	GR	Greece	NO	Norway
BJ	Benin	HU	Hungary	PL	Poland
BR	Brazil	IE	Ireland	RO	Romania
CA	Canada	IT	Italy	RU	Russian Federation
CF	Central African Republic	JP	Japan	SD	Sudan
CG	Congo	KP	Democratic People's Republic of Korea	SE	Sweden
CH	Switzerland			SN	Senegal
CI	Côte d'Ivoire	KR	Republic of Korea	SU	Soviet Union
CM	Cameroon	LI	Liechtenstein	TD	Chad
CS	Czechoslovakia	LK	Sri Lanka	TG	Togo
DE	Germany	LU	Luxembourg	US	United States of America
DK	Denmark	MC	Monaco		
ES	Spain	MG	Madagascar		

SUPPORT FOR A HEART VALVE PROSTHESIS

The invention relates to a support according to the precharacterising clause of Claim 1.

The known prostheses used in cardiac surgery contain a crown-shaped support of plastic, but generally of metal or of both materials. They consist in general of long, often wire-like elements which are predominantly not very elastic and are often joined by soldering or welding. This results in poor adaptability, especially since the joints then become brittle, but in some cases also relatively poor tolerance, not least because the textile covering generally applied to the support then requires several seams in order to hold securely on the wire skeleton of the support, with the result that strength problems may also occur and manufacture is made more difficult. Typical heart valve prostheses of this type are described in U.S. Patent 3,570,014 or U.S. Patent 3,755,823.

It is the object of the invention to design a support for a heart valve prosthesis of the type stated at the outset in such a way that the adaptability and tolerance are improved, strength problems being avoided. This is achieved according to the invention by the characterising features of Claim 1.

The two-dimensional embodiment ensures both flexibility and adaptability, the one-piece embodiment making solder connections or the like superfluous, which is advantageous on the one hand for the strength and durability and on the other hand for easier manufacture.

The elasticity and flexibility of the support arms is further improved by the embodiment according to Claim 2. The embodiment having indentations between projections, according to Claim 3, permits the accommodation of excess biological heart valve

material, which is fastened in a known manner to the support or to its textile covering. It is true that similar indentations were present also in an embodiment according to U.S. Patent 4,259,753, which attempted to overcome the previous disadvantages by avoiding long support arms, and of course with acceptance of the other disadvantages mentioned.

In particular, the embodiment, according to the invention, of the support provides such great adaptability that the heart valve prosthesis can be used equally, in the position of mitral or trichospidal valves.

Further details of the invention are evident from the following description of embodiments shown schematically in the drawing.

Fig. 1 shows a suport according to the invention before attachment of the biological heart valve material and

Fig. 2 shows the developed view of a support formed according to the invention, for which

Fig. 3 to 5a show various cross-sectional forms.

Fig. 1 shows a heart valve prosthesis 1 having an annular support 1a according to the invention in an oblique view with partly removed textile covering 3, which covers the annular support 1a together with a collar 2 mounted thereon. As can be seen, the support 1a consists of flat material, in particular of a thermoplastic, so that it can be produced easily and economically, for example by injection moulding.

The support 1a possesses, in a known manner, three axially projecting support arms 4, the free ends of which are rounded in the manner to be described subsequently with reference to Fig. 2. Projections 5 and indentations 6 are arranged alternately at the axial end of the support 1a, opposite the support arms 4, in which indentations any excess biological heart valve material, which is to be flattened in a

conventional manner over the support arms and is to be fastened to the collar 2, can be accommodated. As will be explained subsequently, the support 1a - in contrast to the prior art - is relatively flexible and elastic, and expediently only the middle region between the base region 4a of the support arms 4 and the indentations 6 can be reinforced, as is evident from Fig. 4a and 5a.

The textile covering 3 is expediently elastic and consists, for example, of a network fabric, because such a fabric has sufficient intrinsic elasticity - even when conventional, biologically tolerated textile material is used. In practice, a USCI product, Adavison, from C.R. Bard, Catalogue No. 007831, has proved expedient. This is all the more surprising since nonelastic coverings have been chosen to date; however, it will subsequently become clear that the choice of elastic material results in a simplification in the manufacture of the heart valve prosthesis, improved safety with respect to tearing of seams and a smaller number of such seams, which also improves the tolerance of the prosthesis. This is because in many cases a concealed (and therefore invisible) circumferential seam in the region of the collar 2 will be sufficient, if necessary with a vertical seam 7.

From the developed view of the enclosed support 1a according to Fig. 2, it can be seen that the indentations 6 are located exactly opposite the support arms 4, on the same generatrix 8 which forms a common axis of symmetry. The rather flat projections 5 are located between the indentations 6. The generatrices 8 preferably form a gentle cone, the geometry of which will be discussed with reference to Fig. 3 to 5a. The height H from the outermost tip of the support arms 4 to the ends of the projections 5 is smaller than the maximum diameter of the support 1a shown in Fig. 1.

To make it easier to pull on the material 3 - with an optimal anatomical fit - it is expedient if the

support arms 4 are rounded at their free ends with a radius R which corresponds to not more than one eighth of the diameter of the support 1a - measured in the region of the collar 2 shown in Fig. 1. On the other hand, it is advantageous if the indentations 6 are relatively flat, the radius of curvature 2R prefrably corresponding to not more than twice the radius of curvature R of the support arms 4. The collar 2 consisting of textile or plastic material is expediently mounted between the two circumferential lines 9 and 10, the circumferential line 9 being located underneath the base 4a of the support arms 4 - preferably at a distance a1 of about 1 mm - the circumferential line 10 advantageously being located somewhat further, for example a distance a2 of about 2 mm, from the edges of the indentations 6. The height h of the indentations 6, that is to say the height of the arrow from the free end of the projections 5 to the lowest point of the indentation 6, should expediently be not more than 0.2 mm.

The wall thickness W of the flat support 1a can be relatively uniform and not more than 1 mm, but Fig. 3 to 5a are intended to show that nonuniform wall thicknesses are also possible within the scope of the invention. It should also be mentioned that Fig. 2 shows an equidistant arrangement of the support arms 4, i.e. an arrangement distributed symmetrically over the circumference of the annular element 1a, but that, as has also already been proposed - asymmetric arrangements are likewise possible. Thus, by means of different spacings between the support arms 4, the fact that the biological material is generally not uniformly available for the heart prosthesis is taken into account. For example, if the spacing of the three arms increases in the clockwise or counterclockwise direction, an angular sequence of 110°, 120° and 130° proving particularly advantageous, different biological

circumstances can be catered for with these two embodiments.

Fig. 3 shows a section through the support 1a, in which the arms 4 make an angle α, preferably of not more than 8°, with a longitudinal axis or with a line L parallel thereto, so that the vertical angle of the support arms 4 converging from two opposite sides of the annular element 1a is finally 2α. In this embodiment, the wall thickness W in the region of the support arms 4 is relatively uniform; it may taper slightly towards the free ends of the arms 4, while the region located underneath the base 4a in between can be reinforced in its cross-section A, that is to say arched inwards. This gives the support arms 4 increased mobility and elasticity which supports its function at a point in constant movement and, owing to its greater adaptability, makes the prosthesis more suitable for use in a very wide range of positions.

In the case of Fig. 4, too, the outer surface of the support arms 4 is conical with respect to the longitudinal axis of the support 1a, as is preferred. Here, however, the internal diameter of the support is the same over the height of the support arms 4, so that the inner cavity - in the region of the support arms 4 - is to be regarded as cylindrical. In addition to this conical embodiment of the upper support arm region of the support 1a, the lower region too, which includes the projections 5 and the indentations 6, can be in the form of a cone which opens in a downward direction and has a slightly larger cone angle $\alpha 1$, where $\alpha 1$ may be, for example, about 2° larger than α. If, for example, α is 6°, $\alpha 1$ is 8°.

The transition from the upper region of the support arms 4 to the lower region of the projections 5 is preferably via the outer (and inner) curvature. The radius R1 of this curvature is not critical and may

be, for example, 15 to 45 mm. This also improves the retention of the collar 2 - where it is used - and of course the transition from the upper to the lower region is therefore close to the line 10 described above with reference to Fig. 2.

As shown in Fig. 4a by means of a section, an annular region 11 which has a cross-section tapering inwards to a point and imparts greater stability there to the support 1a while fully retaining the elasticity of the support arms, can be provided between the projecting support arms 4 and the projections 5 forming - similarly to Fig. 4 - a lower cone of relatively great divergence. For reasons relating to medical technology, however, a continuously rounded transition is generally provided between the upper and the lower region. The fact that the wall thickness of the support arms 4 tapers at an angle $\alpha 2$ towards their free ends in such a way that the free end is, for example, about 20% narrower than the base of the particular support arm 4 helps to increase the elasticity in the case of Fig. 4 and 4a.

If Fig. 4a also shows an annular region 11 tapering inwards to a point, it is of course true that an inner curvature, for example having the stated radius R1, is preferable. Larger radii of, for example, 30 mm (cf. Fig. 5) are preferable to smaller radii (cf. Fig. 5a) because they permit better adaptation to the particular function. Thus, the embodiment according to Fig. 5 appears to be optimal; it has an upper cone having a vertical angle of, for example, 6° and a lower cone having a vertical angle of, for example, 8°, in conjunction with tapering of the support arms 4 towards their free ends, and an inner curvature having a radius R1.

In this sense, it is possible first to prefabricate supports 1a of different diameters, preferably from 17 mm to 33 mm at the base B. In order

subsequently to form a heart valve prosthesis 1 shown in Fig. 1 therefrom, a textile covering 3 must be provided - in the manner described. In practice, a human (if desired also an animal) pulmonary or aortic valve is stored either in a nutrient solution (together with antibiotics and other substances) and is sewn to the prosthesis shown shortly before use; alternatively, the already combined components of the prosthesis are stored or frozen together in a nutrient solution until they are required. This also ensures a high rate of cell survival, and the prostheses produced in this manner can be used in four different positions.

A large number of modifications are possible within the scope of the invention: although the tapering with the angle $\alpha 2$ (Fig. 4) was described with reference to the support arms 4, it is advantageous if the projections 5 also taper, as illustrated in particular by the preferred embodiment according to Fig. 5, with the result that these projections 5, too, impart improved elasticity.

PATENT CLAIMS

1. Support of a plastic material for a heart valve prosthesis, which support has, at one axial end, axially projecting support arms distributed over the circumference and rounded at the free end, having a covering, for fastening biological heart valve material, characterised in that the support (1a) is formed as a single piece from flat, closed, preferably thermoplastic material which itself has an approximately hollow cylindrical or hollow conical shape.

2. Support according to Claim 1, characterised in that its wall thickness (W) tapers towards the free ends of the support arms (4).

3. Support according to Claim 1 or 2, characterised in that axial indentations (6) are formed in the axial support end opposite the free end of the support arms (4), between which indentations projections (5) are located, and that the normal distance from the free end of a projection (5) to the lowest point of the indentation (6) adjacent to it is not more than 0.2 mm.

4. Support according to Claim 3, characterised in that the wall thickness (W) of the support (1a) tapers towards the free ends of the projections (5), starting from a reinforced annular region, and/or the projections (5) diverge conically in the axial direction by a predetermined angle ($\alpha 1$) of not more than 8°, preferably not more than 4°.

5. Support according to any of the preceding Claims, characterised in that the support arms (4) converge towards one another conically in the axial direction by a predetermined angle ($\alpha 2$) of not more than 8°, preferably not more than 6°.

6. Support according to any of the preceding Claims, characterised in that at least one of the

following features is present:

a) the support arms (4) are rounded at the free end, the radius of curvature (R) being not more than one eighth of the diameter of the support (1a) - measured at the base (4a) of the support arms (4);

b) the total height (H) of the support (1a) corresponds to not more than its diameter;

c) the wall thickness (W) of the support (1a) is not more than 1 mm.

7. Support according to Claim 6, characterised in that the indentations (6) are rounded, the radius of curvature (2R) preferably corresponding to not more than twice the radius of curvature (R) of the free ends of the support arms (4).

8. Support according to any of the preceding Claims, characterised in that the support arms (4) are different distances apart, said spacing corresponding in particular to an arithmetic series.

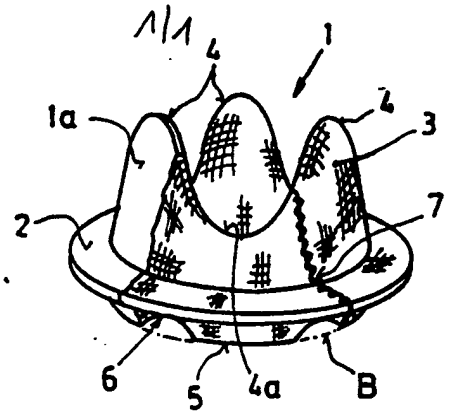


Fig. 1

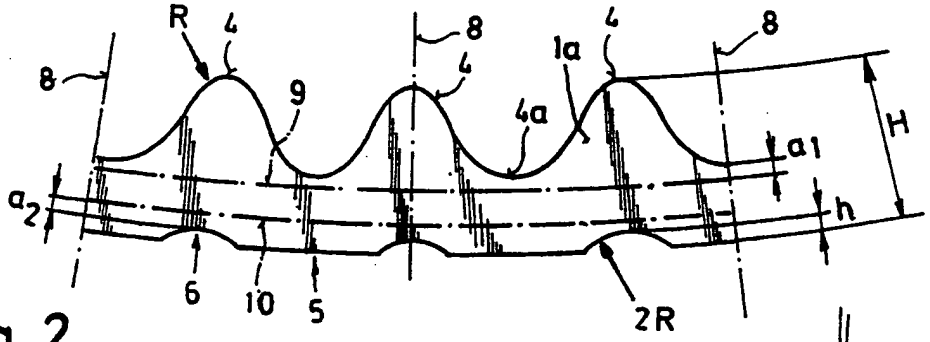


Fig. 2

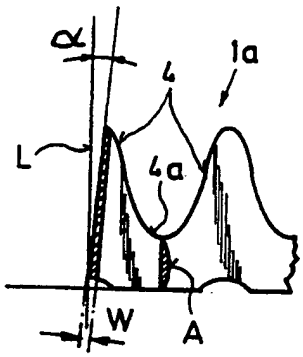


Fig. 3

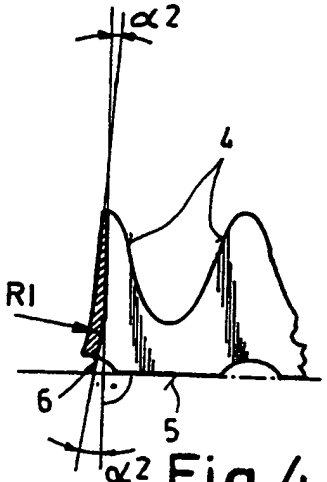


Fig. 4

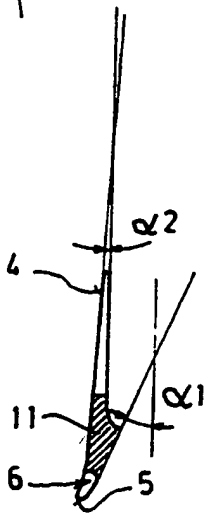


Fig. 4a

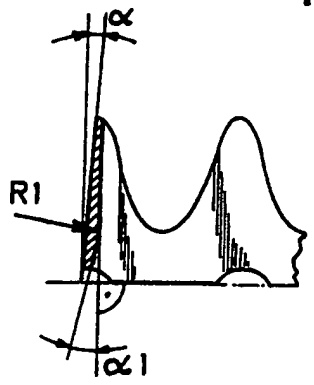


Fig. 5

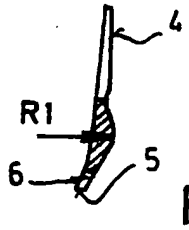


Fig. 5a

INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 92/01017

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5, A61F2/24

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X A	US,A,3 983 581 (ANGELL) 5 October 1976 see column 3, line 45 - column 4, line 4 see column 4, line 31 - line 54; figures 3-5	1,6 3,7
A	EP,A,0 143 246 (WEINHOLD) 5 June 1985 see the whole document	1,3,6,7
A	US,A,3 938 197 (MILO) 17 February 1976 see figures 4,7	2
A	FR,A,2 451 189 (LIOTTA) 10 October 1980 cited in the application	
A	DE,A,1 939 121 (HANCOCK) 19 March 1970 cited in the application	

[10] Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
04 SEPTEMBER 1992	14. 09. 92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	KLEIN C.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. EP 9201017 SA 60341

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 04/09/92
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-3983581	05-10-76	US-A- 4035849	19-07-77
EP-A-0143246	05-06-85	AU-B- 572892	19-05-88
		AU-A- 3340784	02-05-85
		CA-A- 1228203	20-10-87
		DE-A- 3485305	09-01-92
		JP-A- 60096261	29-05-85
US-A-3938197	17-02-76	None	
FR-A-2451189	10-10-80	US-A- 4259753	07-04-81
DE-A-1939121	19-03-70	FR-A- 2018143	29-05-70
		GB-A- 1243293	18-08-71
		US-A- 3570014	16-03-71
		US-E- RE30912	27-04-82